

REMARKS

This Amendment is submitted in response to the final Office Action mailed on January 30, 2008 and the Advisory Action mailed on July 7, 2008. A Request for Continued Examination ("RCE") (\$810.00) and petition for a three month extension of time (\$1,050.00) are submitted herewith. Please note we paid a one month extension fee (\$120.00) on May 29, 2008. The Director is authorized to charge \$1,740.00 for the RCE and the petition for extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-746 on the account statement.

Claims 1-4, 6-9 and 11-26 are pending in this application. Claims 17-21 were withdrawn from consideration and Claims 5 and 10 were previously canceled without prejudice or disclaimer. In the Advisory Action, the previous anticipation and obviousness rejections were maintained. In the Final Office Action, Claims 1-4, 6, 8-9, 11-16, 22 and 24-26 were rejected under 35 U.S.C. §102. Claims 1-4, 6-9, 11-16 and 23-26 were rejected under 35 U.S.C. §103. In response, Claims 1, 9, 15, 22, 24 and 26 have been amended and Claims 6-7 have been canceled without prejudice or disclaimer. These amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the final Office Action, Claims 1-4, 6, 8-9, 11-15, 22 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,965,183 to Hartal et al. ("*Hartal*"). In response, Applicants have amended independent Claims 1, 9, 15 and 22. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Currently amended independent Claims 1, 9 and 15 recite, in part, a composition comprising at least one carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof. Similarly, independent Claim 22 recites, in part, a method for improving skin health comprising the step of administering to a patient in need of improved skin health at

least one carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80, wherein the carotenoid compound is selected from the group consisting of lycopene, zeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof. These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 6, lines 26-30; page 7, lines 1-3; page 11, lines 28-29; page 12, lines 3, 9-10 and 16.

Carotenoids are natural products that have beneficial effects such as alleviating chronic diseases. See, Specification, page 1, lines 12-13. Isolated or enriched carotenoid compounds extracted from a natural source such as a plant or an animal are already known in the art. See, Specification, page 1, lines 11-16. However, the carotenoids in these isolated compounds are insufficiently bioavailable such that their beneficial effects are not fully realized. See, Specification, page 1, lines 15-17. In contrast, the present claims provide a carotenoid compound with improved bioavailability and bioefficacy. See, Specification, page 2, lines 1-4. The *cis*-isomer content of isolated or enriched carotenoid compounds extracted from plants or animals is low. See, Specification, page 5, lines 20-22. Therefore, once the isolated or enriched carotenoid compounds are extracted from the plant or animal, they are further subjected to microwave irradiation or other non-thermal treatments such as solubilisation followed by phase separation in order to increase the *cis*-isomer content of the carotenoid. See, Specification, page 6, lines 4-9, 14-17 and 26-30. By further processing the isolated carotenoid compound to increase its *cis*-isomer content such that the *cis:trans* isomer ratio is at least 20:80, the bioavailability and/or bioefficacy of the carotenoid compound is increased as compared with the isolated carotenoid compound alone. See, Specification, page 6, lines 4-9; page 7, lines 1-7. Specifically, the carotenoid-containing material enriched in *cis*-isomers is more soluble in lipids and organic solvents, is less prone to crystallization, and has a lower tendency to aggregate. See, Specification, page 3, lines 5-10. In contrast, Applicants respectfully submit that *Hartal* fails to disclose each and every element of the present claims.

For example, *Hartal* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio is at least 20:80 as required, in part, by currently amended independent Claims 1, 9, 15 and 22. Instead, *Hartal* only

discloses, at best, a carotenoid isolated or enriched from plants, animals or other natural sources. See, *Hartal*, column 2, lines 20-33 and 60-64. The Patent Office asserts that “[a]s long as one of the carotenoid compounds is isolated then the claim is anticipated.” See, Advisory Action, Item 11, lines 2-3. However, Applicants respectfully submit that a carotenoid compound that is merely isolated or extracted from a plant or animal source, such as that disclosed in *Hartal*, is distinguishable from the compound of the present claims. *Hartal* is entirely directed to lycopene concentrates and oleoresins. See, *Hartal*, Abstract, line 1; column 2, lines 60-64. The isolated lycopene-containing compound is extracted from any suitable source and may be a watermelon or tomato oleoresin. See, *Hartal*, column 2, lines 60-62; column 4, lines 59-61. The *cis:trans* isomer ratio in an isolated carotenoid compound such as tomato oleoresin is low, for example 7:93. See, Specification, page 5, lines 20-22. In contrast, the present claims provide an isolated carotenoid compound such as tomato oleoresin that is further processed to increase the *cis:trans* isomer ratio to at least 20:80. See, Specification, page 7, lines 1-3. Nowhere does *Hartal* disclose or suggest a carotenoid-containing compound enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio of the carotenoid compound is at least 20:80, nor does the Patent Office cite support for such claimed element. In fact, *Hartal* never discloses any *cis:trans* isomer ratio of its carotenoid-containing material. Therefore, *Hartal* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio is at least 20:80 as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6, 8-9, 11-15, 22 under 35 U.S.C. §102 to *Hartal* be withdrawn.

In the Office Action, Claims 1-4, 6, 8-9 and 11-14 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,329,557 B1 to Rodriguez et al. (“*Rodriguez*”). In response, Applicants have amended independent Claims 1 and 9. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

For example, *Rodriguez* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio is at least 20:80 as required, in part, by currently amended independent Claims 1 and 9. As acknowledged by the Patent Office, *Rodriguez* merely discloses, at best, carotenoids isolated or extracted from

plants, crustaceans, birds, algae and bacteria. See, Final Office Action, page 4, lines 5-7. However, the Patent Office asserts that *cis* forms of carotenoids occur naturally and, as such, isolation of carotenoids leads to the enrichment of *cis* forms of the carotenoids. See, Final Office Action, page 4, lines 10-11. Applicants respectfully submit that, even if some carotenoids naturally contain *cis* isomers, the ratio of *cis:trans* isomers of the isolated carotenoid compound is low. See, Specification, page 5, lines 20-22. The mere isolation and purification of such carotenoids does not alter the *cis:trans* ratio of the carotenoid itself but merely increases the percentage of carotenoid in the composition. In order to alter the *cis:trans* isomer profile of the carotenoid compound, the isolated carotenoid compound must be subjected to a further treatment intended to modify the isomer profile of the compound such that the *cis:trans* isomer ratio is at least 20:80. See, Specification, page 6, lines 23-28; page 7, lines 1-3. *Rodriguez* merely discloses “processes for isolation and purification of lutein and [x]eaxanthin from natural sources.” See, *Rodriguez*, column 4, lines 1-3. Nowhere does *Rodriguez* disclose or suggest further treatment of the isolated or purified carotenoids to modify their isomer profile. As such, *Rodriguez* fails to disclose or suggest a carotenoid-containing material enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio is at least 20:80 as required, in part, by independent Claims 1 and 9.

Furthermore, even if, as the Patent Office asserts, the isolation of carotenoids naturally containing *cis* isomers leads to the enrichment of *cis* forms of the carotenoids, *Rodriguez* only discloses, at best, that lutein may naturally contain *cis* isomers. See, *Rodriguez*, column 6, lines 39-41. Nowhere does *Rodriguez* disclose or suggest *cis* isomers or any other carotenoid compound. However, Applicants have amended independent Claims 1, 9, 15, 22, 24 and 26 to remove any reference to lutein. As such, Applicants respectfully submit that the isolated compounds of *Rodriguez* are not, either inherently or expressly, enriched in *cis*-isomer of the carotenoid compound such that the *cis:trans* isomer ratio is at least 20:80 as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6, 8-9 and 11-14 under 35 U.S.C. §102 to *Rodriguez* be withdrawn.

In the Office Action, Claims 1-4, 6, 8-9, 11-16, 22 and 24-26 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,310,554 to Haigh (“*Haigh*”). In response,

Applicants have amended independent Claims 1, 9, 15, 22, 24 and 26. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

For example, *Haigh* fails to disclose or suggest a carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof as required, in part, by currently amended independent Claims 1, 9, 15, 22, 24 and 26. As acknowledged by the Patent Office, *Haigh* only discloses beta-carotenes purified from plants. See, Office Action, page 4, lines 21-23; page 5, lines 1-20. Nowhere does *Haigh* disclose carotenoids selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof.

Nevertheless, the Patent Office asserts that *Haigh* anticipates the present claims because it teaches at least one carotenoid enriched in *cis*-isomer content of the carotenoid compound. See, Office Action, page 5, lines 18-20. However, the only carotenoid compound disclosed by *Haigh* is beta-carotene. In contrast, the present claims recite, in part, a carotenoid compound selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof. Since beta-carotene is not one of the enumerated carotenoid compounds, *Haigh* fails to disclose or suggest a carotenoid-containing material, enriched in *cis*-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, phytofluene, phytoene, and combinations thereof as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6, 8-9, 11-16, 22 and 24-26 under 35 U.S.C. §102 to *Haigh* be withdrawn.

In the Office Action, Claims 1-4, 6-9, 11-16 and 23-26 are rejected under 35 U.S.C. §103(a) as unpatentable over *Haigh*. The Patent Office asserts that using oleoresin composition to treat skin and combining the claimed ingredients into a single composition are obvious modifications of *Haigh*. See, Office Action, page 7, lines 15-21; page 8, lines 1-6. However, as discussed previously, *Haigh* fails to disclose or suggest a carotenoid-containing material,


enriched in *cis*-isomer of the carotenoid compound, wherein the carotenoid compound is selected from the group consisting of lycopene, xeaxanthine, beta-cryptoxanthin, capsanthine, canthaxanthine, lutein, phytofluene, phytoene, and combinations thereof as required, in part, by currently amended independent Claims 1, 9, 15, 22, 24 and 26. Instead, *Haigh* is entirely directed to methods for the preparation of highly purified beta-carotene and compositions containing the highly purified beta-carotene. See, *Haigh*, column 3, lines 25-31. Thus, Applicants respectfully submit that *Haigh* fails to disclose or suggest every element of the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4, 6-9, 11-16 and 23-26 under 35 U.S.C. §103(a) to *Haigh* be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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